CURRICULUM VITAE

FANG LU

HIGHLIGHTS:

- Over 8 years of experience in both pharmaceutical company and contract research organization (CRO) as a lead statistician for numerous clinical projects in various therapeutic areas from phase I-IV including Oncology, Central Nervous System (CNS), Alzheimer's Diseases, Cardiovascular (CV), Attention Deficit Hyperactivity Disorder (ADHD) and Binge Eating Disorder (BED), etc.
- Over 8 years of experience in both pharmaceutical company and contract research organization (CRO) as a lead statistician for numerous clinical projects in various therapeutic areas from phase I-IV including Oncology, Central Nervous System (CNS), Alzheimer's Diseases, Cardiovascular (CV), Attention Deficit Hyperactivity Disorder (ADHD) and Binge Eating Disorder (BED), etc.
- Extensive knowledge and hands-on experiences in clinical study documentations including protocol development support, statistical analysis plan (SAP) creation, and clinical study report (CSR) writing, reviewing manuscripts and involving in Advisory Committee Meeting preparation.
- Familiar with various registration activities including supporting to answer regulatory agencies' questions, Integrated Summary of Safety (ISS), Integrated Summary of Efficacy (ISE), Investigational New Drug (IND), and New Drug Application (NDA).
- Strong statistical knowledge, proficient skills in SAS programming with expertise in Base, Stat, Graph, SQL, Macro and macro library build-up and maintenance, and hands-on knowledge in Clinical Data Interchange Standards Consortium(CDISC) including SDTM and ADaM.

PROFESSIONAL EXPERIENCE:

September 2013 to Present
SHIRE, Chesterbrook, Pennsylvania

Statistician Consultant

- Lead for designing and generating statistical outputs based on regulatory agency's requests and meeting minutes of the key opinion leaders to support BED Advisory Committee Meeting for NDA.
- Contribute to the BED US and Brazil labeling for the Adverse Drug Reactions sections, as well as the VYVANSE® Company Core Data Sheet (CCDS).
- Provide statistical supports for BED phase III, ADHD double-blind active-control phase III studies, and work on ad hoc requests for ADHD projects.
- Review CSR and contribute to statistical relevant sections; review posters and manuscripts for publications review BED phase III study results for publishing on the government's website to fulfill the regulatory agency's requests; review periodic finance accruals provide by CRO.
- Perform sample size calculations using software or simulation to support study designs.
- Organize and coordinate ISS and ISE activities.
- Design and generate statistical tables, figures and analysis datasets for ISS, individual studies and ad hoc requests; validate CRO's/coworkers' work.
- Work on innovation methods, such as multiple imputation for missing values and mixed model for repeated measure for ADHD studies.

September 2011 to March 2013
CELGENE CORPORATION, Summit, New Jersey

Statistician Consultant

- Provided statistical support to Clinical Pharmacology and Experimental Medicines groups. Worked on early phase studies, and the parts that embedded in Phase II/III studies pertaining to PK, and PK/PD.
- Used quantitative methodologies for exploration, modeling, analysis, and interpretation of PK and PK/PD data.
- Developed SAP and guide team members to perform relevant statistical analyses accordingly.
- Reviewed protocols and wrote statistical sections; reviewed CSR; reviewed CRF and analysis data specifications.
- Performed statistical analysis pertaining to PK, PK/PD, safety and key efficacy endpoints. Used Wilcoxon Rank-Sum test, Hodges-Lehmann's median estimating and constructing confidence intervals for the median difference for appropriate PK/PD parameters, and mixed effects ANOVA models for natural- logarithmically transformed data, etc.
- Coordinated cross-functional tasks to ensure accuracy and efficiency in maintaining, updating and documenting the case report form (CRF) database and the final statistical deliverables.
- Oversaw CRO's work to ensure regulatory requirements compliance, SOPs being followed and appropriately applied for INDs and NDAs.
- Coordinated with the study team and lead programmers to meet the milestones for various projects.
- Developed generic SAS macros at compound level for generating and validating efficacy tables and analysis datasets

March 2007 to September 2011
SYMBIANCE INC., Princeton Jct., New Jersey

Biostatistician

January 2011 to September 2011

- Led a team to work on phase I-IV, ISS, and ISE studies; created and maintained project timelines; coordinated and allocated resources.
- Tracked project budgets; communicated proactively with senior management to address potential changes in work scope.
- Interacted with clients to present project progress and address concerns.
- Developed SAP including shells for the deliverables, and guided the team members to generate the statistical outputs accordingly.
- Performed key statistical analyses on both of descriptive and inferential outputs.
- Reviewed the final listings, tables and graphs for ad hoc requests and studies.

March 2007 to December 2010

- Developed statistical models to analyze clinical data including linear mixed model, generalized mixed model, and survival analysis, etc. for phase II-IV, ISS studies.
- Generated randomization schedules for double-blind clinical trials.
- Reviewed CRFs, data validation manuals and electronic edit check specifications.
- Created SDTM and ADaM specifications for analysis databases.
- Performed PK/PD analysis to C_{max}, AUC, $AUC_{0\text{-}24}$, $AUC_{0\text{-}inf}$, $t_{1/2}$, Steady State, food effect, treatment effect and dosage effect for phase I studies.
- Implemented, reviewed and validated statistical outputs for safety and efficacy results including in-text tables and appendix for CSR.
- Coordinated and performed validation for data transfer processes.

1998 to 2003
XINJIEKOU DEPARTMENT STORE CO., LTD, Nanjing, China

Statistician

- Developed statistical models related to customer segmentations, pricing, and promotion analysis.
- Conducted ad-hoc data analysis for both internal and external clients to gain insight into business needs.
- Pulled data from disparate sources to generate a wide variety of reports on business trend, presented and recommended solutions to senior management.
- Worked closely with the product managers in rolling out new analytics solutions targeted toward better predicting user behavior.
- Led teams of analysts in database marketing projects, guided client expectations, established a timeline for analytic requests, and delivered results.

CERTIFICATIONS:

- SAS Certificated Base Programmer

EDUCATION:

Rutgers University, New Brunswick, New Jersey
M.S. in Statistics, January 2007

Nanjing Audit Institute, Nanjing, China,
B.S. in Accounting, July 2003
A.S. in Economics, July 1998